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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,454	11/02/2001	Paul Jollez	6670/01997	7397

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Mr. S. Peter Ludwig
DARBY & DARBY P.C.
805 Third Avenue
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EXAMINER

HALPERN, MARK

ART UNIT	PAPER NUMBER
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1731

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/008,454

Applicant(s)

JOLLEZ ET AL.

Examiner

Mark Halpern

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

- 1) Acknowledgement is made of Amendment received 12/1/2003. Applicants amend claims 1-13.

Specification

- 2) The amendment filed 12/1/2003, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in the Cross-Reference to Related Application, the phrase "which is hereby incorporated by reference in its entirety" is new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 3) Claims 1-13, are rejected under 35 U.S.C. 103(a) as being unpatentable over Jollez (WO 99/60027) in view of Toshkov (3,954,727), and further in view of Gross (6,344,109).

Claims 1, 3, 6-7, 9: Jollez teaches of a process of making a high purity microcrystalline cellulose without the use of any mineral acids (Jollez, Abstract). Prior to placing the pulp into a reactor, the pulp is prepared by repulping in order to make it less condense, and the pulp is subjected to filtration and trituration. Jollez is silent on cooking of the pulp in a reactor (Jollez, pg. 3, lines 21-26, and pg. 7, line 30 to pg. 8, line 5). Toshkov discloses a process of preparing microcrystalline cellulose, wherein the pulp is cooked in a reactor by heating the reactor to a desired temperature and pressure for a duration of time to obtain a desired degree of polymerization. The process temperature, pressure and duration are disclosed. (Toshkov, col. 2, lines 28-68). It would have been obvious, to one skilled in the art at the time the invention was made, to combine the teachings of Jollez and Toshkov, because such a combination would provide a high quality hydrolysis product of Jollez obtained under stable and safe conditions of Toshkov. After cooking the Toshkov reactor is cooled with water. It would have been obvious that water-cooling of the reactor would necessitate a partial depressurizing of the reactor in order to keep structural integrity of the reactor. The microcrystalline cellulose is separated from the hydrolysate; it is filtered, de-aggregated in a colloid mill, bleached and dried (Toshkov, col. 2, lines 2-63). Jollez and Toshkov are silent on pressing and decompacting of the pulp in the pulp preparation stage. Gross discloses the process of making a cellulose product, wherein pulp is prepared by first blotting of the pulp to remove water from an aqueous solution and then fluffing of the pulp (Gross, col. 9, lines 22-40). This reads on the claimed pressing of the pulp and decompacting of the pulp. It would have been obvious, to one skilled in the art at

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the time the invention was made, to combine the teachings of Jollez and Toshkov with Gross, because such a combination would provide for a starting pulp that is clean and readily reactive in the reactor of Jollez and Toshkov and thus result in a product of high quality and of a high absorbency as disclosed by Gross (col. 1, lines 33-38).

Claim 2: repulping is carried out at a consistency of 2 % (Jollez, pg. 12, line 19).

Claims 4-5: cooking is carried out at temperature range of 200-240 °C for a time period varying from 4 to 24 minutes, depending on the desired degree of polymerization (Jollez, pg. 9, lines 4-7).

Claim 8: it would have been obvious, to one skilled in the art at the time the invention was made, to treat the cooked pulp with sodium hydroxide to eliminate any left over lignin and other impurities.

Claims 10-11: Jollez discloses cellulose bleaching with hydrogen peroxide at temperature of 60-120 °C, pressure from 60 to 120 psi, under air pressure of 60-120 psi, in the presence of magnesium sulfate (Jollez, pg. 9, lines 11-16).

Claim 12: deaggregating, which reads on homogenization, is performed using a colloidal mill (Toshkov, col. 1, lines 40-45).

Claim 13: washing step is disclosed by Toshkov (col. 2, lines 38-40).

Response to Amendment

- 4) Claims 4-13, objection to under 37 CFR 1.75(c) as being in improper form because multiple dependent claims 4-13, is withdrawn in view of amended claims.
- 5) Claims 2-13, objection is withdrawn in view of amended claims.

- 6) Claims 1-13, rejection under 35 U.S.C. 112, first paragraph, is withdrawn in view of amended claims.
- 7) Claims 1-13, rejection under 35 U.S.C. 112, second paragraph, is withdrawn in view of amended claims.
- 8) Claims 1-3, rejection under 35 U.S.C. 103(a) as being unpatentable over Toshkov (3,954,727) in view of Jollez (WO 99/60027) and further in view of Nimz (5,074,960), is withdrawn in view of amended claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 9) Claim 1-13, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/010,907. Although the conflicting claims are not identical, they are not patentably distinct from each other. The present claim 1, which recites "A process for preparing microcrystalline cellulose characterized in that it comprises the

steps of: a) preparing a pulp by repulping, b) pressing the pulp obtained in a) to remove water, c) decompacting the pulp obtained in b), d) feeding the pulp obtained in c) into a pre-heated reactor, e) cooking the pulp with the pre-heated reactor at a predetermined temperature, time and pressure that are selected to obtain a pulp having a stable degree of polymerization, and wherein the cooked pulp is hydrolyzed to form microcrystalline cellulose without the use of any mineral acids, f) partially cooling the reactor by injecting water into said reactor, g) filtering the pulp obtained in f), h) bleaching the pulp obtained in g), i) drying the pulp obtained in h), and j) recovering said microcrystalline cellulose, is not patentably distinct from claim 1 of Application 10/010,907, which recites "A process for preparing a commercially acceptable pharmaceutical grade microcrystalline cellulose comprising: a) repulping a pulp, the pulp having a composition, b) pressing the pulp obtained in a) in order to remove water, c) decompacting the pulp obtained in b), d) feeding the pulp obtained in c) into a pre-heated reactor, e) cooking the pulp in the reactor until the pulp obtains a desired degree of polymerization, said cooking being performed at a temperature, a time, and a pressure which is a function of the desired degree of polymerization and the composition of the pulp, the cooked pulp being hydrolyzed cellulose, f) partially depressurizing the reactor, g) injecting water into the reactor, h) discharging the hydrolyzed cellulose, i) filtering the hydrolyzed cellulose, j) deaggregating the hydrolyzed cellulose of step I); and k) drying the hydrolyzed to form microcrystalline cellulose, said process occurring in the absence of any mineral acids or sulphur dioxide and in the absence of a violent non-selective depressurization" and claim 11 of the

Application which further comprises "bleaching the hydrolyzed cellulose". Also, the present claim 1 is not patentably distinct from claims 11 and 17 of said Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halpern whose telephone number is 571-272-1190. The examiner can normally be reached on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on 571-272-1189. The fax phone number for the organization where this application is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1700.



Mark Halpern
Patent Examiner
Art Unit 1731